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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,097	06/14/2001	Anton Wellstein	38596.0005	3830

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EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	5

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,097	WELLSTEIN, ANTON	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-9**, drawn to an *isolated polypeptide complex* comprising a pleiotrophin protein and a pleiotrophin-receptor protein, classified in class 530, subclass 350, for example.

II. Claims **10-17 and 21-23**, drawn to a *recombinant polypeptide* comprising one or more, but not all regions of a full-length pleiotrophin receptor protein and compositions comprising same, classified in class 530, subclass 300, for example.

III. Claims **18-20**, drawn to a *nucleic acid which encodes the polypeptide of claim 10*, classified in class 514, subclass 23.1, for example.

IV. Claims **24-25 and 29-30**, drawn to a *recombinant polypeptide* comprising one or more, but not all regions of a full-length pleiotrophin protein and compositions comprising same, classified in class 530, subclass 300, for example.

V. Claims **26-28**, drawn to a *nucleic acid which encodes the polypeptide of claim 24*, classified in class 514, subclass 23.1, for example.

VI. Claims **31-36**, drawn to an *antibody* which is reactive against a pleiotrophin protein and hybridoma comprising same, classified in class 435, subclass 326, for example.

VII. Claims **37-46**, drawn to an *antibody* which is reactive against a pleiotrophin receptor protein and hybridoma comprising same, classified in class 435, subclass 326, for example.

VIII. Claims **47-49**, drawn to a *kit* comprising a pleiotrophin-binding region of a pleiotrophin-receptor binding region of a pleiotrophin protein and an additional substance, classified in class 436, subclass 500, for example.

IX. Claims **50-59**, drawn to a *method for evaluating an activity of a substance*, classified in class 514, subclass 2, for example.

X. Claims **60-68**, drawn to a *method for treating a patient* comprising administering to said patient a therapeutically effective dose of a composition comprising a pleiotrophin-receptor protein or fragment thereof, classified in class 514, subclass 2, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions IX and X are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention IX requires search and consideration of evaluating an activity of a substance, which is not required by Invention X. Invention X requires search and consideration of using a protein as a therapeutic agent, which is not required by Invention IX.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the

following reasons. Inventions I, II, III, IV, V, VI, VII, and VIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Although the isolated polypeptide complex of Invention I can be assembled from the recombinant polypeptides of Invention II and Invention IV, or recombinantly expressed using the nucleic acids of Invention III and V, or purified from natural sources using the antibodies of Invention VI and VII, or the kit of Invention VIII it can be made through materially different methods such as chemical synthesis.

5. Although the recombinant polypeptide of Invention II can be assembled from the isolated polypeptide complex of Invention I, or recombinantly expressed using the nucleic acid of Invention III, or purified from natural sources using the antibody of Invention VII, or the kit of Invention VIII it can be made through materially different methods such as chemical synthesis. The nucleic acid of Invention V and the antibody of Invention VI are not required to make or use the recombinant polypeptide of Invention II.

6. Although the nucleic acid of Invention III can be used to recombinantly express components of the assembled from the isolated polypeptide complex of Invention I and the recombinant polypeptide of Invention II it can be used in materially different methods such as gene therapy. The recombinant polypeptide of Invention IV, the nucleic acid of Invention V, the antibodies of Inventions VI and VII, as well as the kit of Invention VIII are not required to make or use the nucleic acid of Invention III.

7. Although the recombinant polypeptide of Invention IV can be assembled from the isolated polypeptide complex of Invention I, or recombinantly expressed using the nucleic acid of Invention V, or purified from natural sources using the antibody of Invention VI, or the kit of.

Invention VIII it can be made through materially different methods such as chemical synthesis. The nucleic acid of Invention III and the antibody of Invention VII are not required to make or use the recombinant polypeptide of Invention IV.

8. Although the nucleic acid of Invention V can be used to recombinantly express components of the assembled from the isolated polypeptide complex of Invention I and the recombinant polypeptide of Invention IV it can be used in materially different methods such as gene therapy. The recombinant polypeptide of Invention II, the nucleic acid of Invention III, the antibodies of Inventions VI and VII, as well as the kit of Invention VIII are not required to make or use the nucleic acid of Invention V.

9. Although the antibody of Invention VI can be used to isolate polypeptides for the isolated polypeptide complex of Invention I or for the kit of Invention VIII or purify from natural sources the polypeptide of Invention IV it can be made through materially different methods such as therapeutic methods. The nucleic acids of Inventions III and V, the polypeptide of Invention II, and the antibody of Invention VII are not required to make or use the antibody of Invention VI.

10. Although the antibody of Invention VII can be used to isolate polypeptides for the isolated polypeptide complex of Invention I or for the kit of Invention VIII or purify from natural sources the polypeptide of Invention II it can be made through materially different methods such as therapeutic methods. The nucleic acids of Inventions III and V, the polypeptide of Invention IV, and the antibody of Invention VI are not required to make or use the antibody of Invention VII.

11. Although the kit of Invention VIII can be used to make isolated polypeptides for the isolated polypeptide complex of Invention I, or act as a source of the polypeptides of Invention II

and IV, it can be made through materially different methods such as therapeutic methods. The nucleic acids of Inventions III and V and the antibodies of Inventions VI and VII are not required to make or use the kit of Invention VIII.

12. Inventions I and each of IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated polypeptide complex of Invention I can be used to make antibodies.

13. Inventions II and each of IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant polypeptide of Invention II can be used to make antibodies.

14. Inventions IV and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant polypeptide of Invention IV can be used to make antibodies.

15. Inventions VIII and each of IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of the kit of Invention VIII can be used to make antibodies.

16. Inventions III and each of IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of IX and X are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IX and X do not recite the use or production of the nucleic acid of Invention III.

17. Inventions IV and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IV and each of X are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention X do not recite the use or production of the recombinant polypeptide of Invention IV.

18. Inventions V and each of IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions V and each of IX and X are unrelated product

and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IX and X do not recite the use or production of the nucleic acid of Invention V.

19. Inventions VI and each of IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and each of IX and X are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IX and X do not recite the use or production of the antibody of Invention VI.

20. Inventions VII and each of IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and each of IX and X are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IX and X do not recite the use or production of the antibody of Invention VII.

21. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

22. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
August 18, 2003